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SOCIOECONOMIC RELEVANCE OF TREATMENT OF CHRONIC HEART FAILURE STAGE NYHA II WITH CRATAEGUS EXTRACT WS® 1442—A PROSPECTIVE 3-YEAR PHARMACOECONOMIC STUDYRychlik R¹, Pfeil T¹, Daniel D¹, Habs M², Klapper HG²¹Institute of Empirical Health Economics, Burscheid, Germany; ²Dr.

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OBJECTIVES: A prospective 3-year observational study has been conducted from 1999 to 2002 to evaluate the pharmacoeconomics of hawthorn-extract treatment of CHF at stage NYHA II. In a cost-utility-analysis (CUA) hawthorn treatment (crataegus extract WS® 1442 as mono- or add-on-therapy) was compared to any other treatment option. Interim results of the study were presented in 2001 and 2002, now the final results are available. **METHODS:** Open, non-randomized observational cohort study with matched-pairs evaluation. The first cohort (Hawthorn-Cohort, HC) comprised patients receiving hawthorn-extract therapy of CHF; in the second cohort (Conventional-Cohort, CC) patients with any other treatment were observed. A number of 116 pairs were necessary for evaluation. For measuring HRQL the EuroQoL-5D was used. Matching criteria were demographic factors and clinical diagnosis. The perspective of the German statutory health insurance funds was applied. **RESULTS:** From 140 study centres 614 patients finished the study (HC: 383; CC: 231). Thereof 153 pairs could be established. Mean direct costs per year for HC and CC amounted to 807€ (median: 511€) and 798€ (median: 525€), respectively ($p = 0.905$). Cost-driving factor was drug acquisition (median HC: 287€, CC: 280€; $p = 0.521$). Significantly fewer prescriptions were done in HC for concomitant ACE-inhibitors, diuretics, digitalis, and beta-blockers. The clinical symptoms dyspnea and fatigue in HC were significantly improved in comparison to CC. During 3 years in the HC 0.240 QALYs were gained (CC: 0.234; $p = 0.867$). Costs per QALY gained amounted to 10,113€ and 10,244€ for HC and CC, respectively. **CONCLUSIONS:** Hawthorn extract WS® 1442 represents an effective treatment alternative in early stages of CHF. Outcomes and costs are comparable to treatment with ACE-inhibitors, diuretics, digitalis, and/or beta-blockers, which are recommended by international guidelines. The symptoms dyspnea and fatigue, which markedly affect the patients' daily activities, can be improved with WS® 1442.

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MODELING THE ECONOMIC IMPACT OF NEW IMPLANTABLE DEFIBRILLATORS WITH A LONGER LIFETIMELamarsalle L¹, Vainchtock A², Le Heuzey JY³, Matalon C⁴, Hazard JR⁴¹GYD institut—division of IMS Health, Lyon, France; ²GYD institut—division of IMS Health; ³Hôpital Européen Georges Pompidou;⁴Guidant France SAS

OBJECTIVES: Vitality 2EL, a new implantable defibrillator (ICD), presents a major advantage: a longer lifetime increasing delay before replacement leading to less reimplantations. This study aims to compare direct medical costs, using this new ICD, Vitality 2EL, versus its main competitors in France. **METHODS:** The first step was to identify among patients included into EVADEF (French national registry of ICD-implanted patients), 7 homogeneous groups according to age at first implant. Then, within each group, we determined average ages and life expectancies using Deale's method and data from the French national statistical institute (INSEE). A Markov model was built using DATA Tree age Pro 2004 taking into account complication rates from literature. Direct medical costs were assessed from the French health care payer's perspective and a 2.5% dis-

count rate was applied. This model was applied to those 7 groups, per single & dual chamber defibrillators (VR & DR), in primary and secondary prevention, and for warranted period (defined by manufacturers) and projected longevity at 15%/50% pacing. **RESULTS:** The model shows an average cost savings range from 34 to 6356€ per patient with Vitality 2EL versus competitors. **CONCLUSION:** Implanting a longer lifetime ICD is clinically beneficial for patients. Furthermore, we demonstrated that it allows cost savings for health care payers.

PCV34

COST-EFFECTIVENESS OF ANTICOAGULATION WITH BIVALIRUDIN VS. HEPARIN AND GLYCOPROTEIN INHIBITORS IN PATIENTS UNDERGOING PERCUTANEOUS CORONARY INTERVENTION IN SWEDENBorg S¹, Persson U¹, Conradson TB², Ericsson K²¹Swedish Institute for Health Economics, Lund, Sweden; ²Nycomed Group, DK-4000 Roskilde, Denmark

OBJECTIVE: To analyse the cost-effectiveness of anticoagulation with bivalirudin compared to heparin and GlycoProtein Inhibitors IIb/IIIa (GPIs) in patients undergoing Percutaneous Coronary Intervention (PCI) in Sweden. **METHODS:** As treatment practice varies between hospitals, e.g. the fraction of patients receiving GPI varies, the model analyses a patient cohort where heparin is combined with GPIs to a variable percentage (% GPIs) and the remaining patients receive heparin monotherapy. The Swedish Council on Technology Assessment in Health Care has estimated that GPIs are being used in a range of 40–50% of all PCIs. Abciximab is the only GPI with indication for PCI in Sweden, and it was therefore used as the comparator. Pooled data from applicable studies (REPLACE-2, EPISTENT, ESPRIT), provided probabilities for the events; death, myocardial infarction (MI), urgent revascularisation (UR) and major and minor bleedings according to the TIMI definitions. Treatment costs (year 2004) were collected for each complication from four Swedish hospitals, and official drug prices from the Swedish pharmacopeia. The model was evaluated using stochastic evaluation, in a Swedish Health Care perspective, in a 30-day time frame. The modelled patient population was on average 63 years of age, 75% male. **RESULTS:** Compared to a 40–50% usage of GPIs, treatment with bivalirudin reduced ($p < 0.05$) all complications (e.g. by 9.3 MIs, 1.9 URs, 14.4 bleedings and 1.5 deaths in 1000 treated patients, of which 40% received a GPI), and at the same time significantly reduced total costs for drugs and health care (87 SEK/patient, 95% CI 21 to 157 at 40% GPIs, or 935 SEK/patient, 95% CI 867 to 997 at 50% GPIs). **CONCLUSIONS:** Treatment with bivalirudin as compared to heparin and GPIs, significantly reduced all studied complications, and resulted in significant savings in total costs of drugs and health care in Sweden.

PCV35

ECONOMIC ASSESSMENT OF SWITCHING TO EZETIMIBE CO-ADMINISTERED WITH SIMVASTATIN IN SPAIN FOR A COHORT OF PATIENTS NOT AT GOAL ON ATORVASTATIN MONOTHERAPYDavies GM¹, Alemao E², Nocea G³, Yin D², Cook JR¹¹Merck & Co., Inc, Blue Bell, PA, USA; ²Merck & Co, Whitehouse Station, NJ, USA; ³Merck, Sharp & Dohme de España, Madrid, Spain

OBJECTIVE: Assess cost-effectiveness of switching patients to ezetimibe 10mg (EZ10) co-administration with simvastatin 20 mg (S20) versus an atorvastatin titration strategy (patients are titrated to goal or maximum atorvastatin dose of 80 mg) in CHD and CHD equivalent patients not at goal with atorvastatin 10mg (A10) monotherapy. Method: Decision-analytic model

developed to project lifetime costs and benefits of lipid therapy. Clinical trial data were used to estimate LDL-C reductions for different treatment strategies. Effect of LDL-C reductions on CHD event rates was estimated using Framingham equations and Spanish Instituto Nacional de Estadística data on nonCHD-related mortality. Direct costs of CHD events in Spain, Spanish prices for simvastatin, atorvastatin and EZ10 were used to project lifetime costs. Model was run for a population consisting of all CHD and CHD-equivalent patients started on A10 in an observational Lipid Lowering Treatment study conducted in Spain, and not at LDL-C goal after 60 days of treatment. **RESULTS:** For these patients $N = 54$ (mean age 62.5 years, 64.8% male, lipid profile on A10 mean LDL-C 148.7mg/dl, TC 225.9mg/dl, HDL 45.9mg/dl), switching to EZ10 co-administered with S20 compared to atorvastatin titration is projected to increase the life expectancy from 15.99 to 16.31 years for CHD patients and from 18.11 to 18.23 years for CHD equivalent patients with a discounted incremental cost per life year gained of 7,855 EURO for CHD patients and 15,356 for CHD equivalent patients. **CONCLUSION:** Switching to EZ10 co-administered with simvastatin for CHD and CHD equivalent patients not at goal on atorvastatin is projected to be a cost-effective alternative to atorvastatin titration.

PCV36

ECONOMIC EVALUATION OF PRIMARY PREVENTION OF CVD EVENTS WITH STATINS IN ITALY

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OBJECTIVES: Cardiovascular diseases (CVD) are the leading cause of morbidity and mortality. Treatment with statins has shown to be effective in controlling cholesterol levels in dyslipidemic subjects and in preventing CVD. The objective of this analysis was the evaluation of the economic impact of the CVD primary prevention with statins in Italy. **METHODS:** Alternatives: market mix for statins (low dosages assumed as initial dosages) marketed in Italy (weighted with the current market shares) compared with no intervention. Population: sample of high-risk subjects with an absolute CV risk level $\geq 2\%$ per year, derived from a population study conducted in the Verona area in Italy. Perspective: National Health Service (NHS). Technique: cost-effectiveness analysis, making economic and health projections in a hypothetical cohort of 1000 subjects in primary prevention; an incremental cost per life year gained (ICER LYG) has been calculated. Time: 10 years. Costs: drugs and direct medical costs quantified in using NHS tariffs expressed in Euro 2003. Effects: the effects of different statins in controlling cholesterol levels, as measured with the CURVES study (Jones P et al, 1998) has been used to model coronary (CHD) morbidity and mortality from CVD with the Framingham risk equations (Anderson KM et al, 1990). **RESULTS:** A primary CVD preventive intervention with statins in a hypothetical cohort of 1000 high-risk subjects can avoid 70 CHD events and 28 CVD deaths, thus projecting 138 LYG. After having considered costs for drugs (4,789,542€) and savings due to events avoided (319,722€), the net cost of the intervention is 4,469,820€ with a ICER LYG of 32,458€. **CONCLUSIONS:** The cost-effectiveness profile of CVD primary preventive intervention with statins is in the range of what is considered cost-effective in absolute values by the scientific community.

PCV37

ECONOMIC EVALUATION OF TRANSESOPHAGEAL ECHOCARDIOGRAPHY (TEE) GUIDED CARDIOVERSION IN THE ANTICOAGULATION IN CARDIOVERSION USING ENOXAPARIN (ACE) TRIAL FROM THE PERSPECTIVE OF STATUTORY HEALTH INSURANCE (SHI) IN GERMANY

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OBJECTIVES: To estimate—from the German SHI perspective—economic consequences of using the low-molecular-weight heparin enoxaparin subcutaneously (ENOX) instead of intravenous unfractionated heparin followed by oral phenprocoumon (UFH/PPC) for anticoagulation in patients undergoing TEE-guided early electrocardioversion from nonvalvular atrial fibrillation (AF). **METHODS:** As ENOX is noninferior to UFH/PPC in preventing deaths and ischemic, embolic, and hemorrhagic events [Stellbrink C, et al. ACE trial. Circulation 2004], a cost-minimization analysis (CMA) was performed. The target variable “incremental cost for ENOX versus UFH/PPC” was quantified using a modelling approach based on decision-tree technique. The CMA encompassed 28 (26–30) treatment days with phase I of 5 (3–8) days comprising diagnostics, initiation of anticoagulation, and cardioversion. Phase II with the remaining days comprised continued anticoagulation. Resource use was verified by a survey in the in- and outpatient sectors. Costs were given by SHI expenses and were quantified by multiplying utilised resource items by the price or tariff of each item, according to German Health Care regulations. **RESULTS:** In the base-case analysis, phase I was outpatient based for the majority of ENOX patients opposed to inpatient treatment for all UFH/PPC patients, whereas phase II was entirely outpatient based for both patient groups. There were savings of 579€ per patient with ENOX (892€) compared to UFH/PPC (1471€). Comprehensive sensitivity analyses (impact analysis, Monte Carlo simulation) showed the robustness of the model. Expenses for the inpatient-based phase I with UFH/PPC had by far the greatest influence on the extent of savings obtained. Simultaneous random variation of all model parameters within their empirically given intervals revealed savings obtained by ENOX in 93% of 10,000 simulated comparisons versus UFH/PPC. **CONCLUSIONS:** In TEE-guided early electrocardioversion of nonvalvular AF, anticoagulation with ENOX offers SHI in Germany an enormous saving potential when used instead of UFH/PPC.

PCV38

COSTS OF MYOCARDIAL INFARCTION TREATMENT IN RUSSIAN FEDERATION

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OBJECTIVE: To calculate costs for patients with myocardial infarction (MI) in common medical practice in Russian Federation. **METHODS:** Data on resource use for hospital treatment of patients with acute myocardial infarction were extracted from 99 medical charts at 3 hospitals at Moscow, Tula and Vladimir. Data on resource use for out-patient follow-up for patients after acute myocardial infarction were identified according to experts' opinion. A total of 12 experts filled in the questionnaire for identifying typical follow-up strategy for 1.5 years after MI. Direct medical costs were calculated on the basis of price-lists for medical services and median prices for drugs given in a wholesale pharmaceutical informational bulletin. **RESULTS:** Median